Consumer Learning - Learning Framework of Concepts and eLearning Outcomes

Concept 1: **Understand clinical trial context, concepts and protocols** This concept will provide a foundation of cancer knowledge and an understanding of the cancer clinical trial process. Consumers will be introduced to the fundamentals of cancer research design and will learn about basic statistical concepts and terms. Consumers will not be expected to become statistical experts, but will be provided with experiences that will further their ability to understand and interpret research results.	**Concept 2:** **Communicating trial information** Skills in communicating information about clinical trials are essential to consumers providing advice in the context of Cancer Clinical Trial Research. This concept will assist consumers to use and apply these skills and knowledge in the critical appraisal of participant information and capably fulfill the role of the consumer in a Cancer Clinical Trial Group (CCTG).	**Concept 3:** **Develop skills for participating in the cancer clinical trial research process** This concept will assist consumers effectively participate in the Cancer Cooperative Trial Group (CCTG) decision making processes and contribute to committees
Capability 1.1: Knowledge of Cancer Consumers in CCTGs build on their knowledge of Cancer and specific types and further their understanding of the epidemiology of cancer.	***Capability 2.1: Understand the context of 'informed consent'*** Consumers learn about the legal nature and the elements of informed consent. They examine and explore the risks and costs associated with decision making, and appraise scenarios that may not fulfill the requirements of valid, competent and voluntary consent.	***Capability 3.1: Effective committee membership*** Consumers appreciate and understand how research committees function, the importance of the committee process and the expectations of an effective committee member. They learn about the need to be organized, prepared and manage time effectively, prioritize and complete actions in agreed timeframes, comment on documentation and other responsibilities that are consistent with the committee terms of reference.
Capability 1.2: Understanding of Cancer research design Consumers learn about the fundamentals of cancer research design including basic statistical concepts and terms. They explore the concepts of randomization, p values and measures as well as different types of cancer clinical research design.	***Capability 2.2: Critically appraise Cancer Clinical Trial participant information*** Consumers examine and review participant information and consent forms, discuss and analyze the suitability of language, format and presentation as materials that are 'easy to read' are more acceptable to a potential research participant. Consumers use checklists that assist them identify ambiguous phrases, technical jargon and socially or culturally inappropriate language. Consumers develop appraisal skills that will assist them to decide if the aims of a study, the treatment schedule, side effects and, risks as set out in the protocol are consistent with the participant information.	***Capability 3.2: Effective interpersonal communication skills in meetings and committees*** Consumers understand the need to develop effective written and verbal communication skills and the value of demonstrating appropriate interpersonal behaviour and professional conduct. Committee members with effective interpersonal skills are familiar with terminology of the CCTG specialty through using glossaries, and seeking clarification as required.
Capability 1.3: Understanding of Cancer Clinical Trials Consumers learn about clinical trials and cancer clinical trials research nationally and internationally, funding opportunities within Australia and the role of government and non-government organizations involved in cancer research. They understand about cancer specific clinical trials and the functions of the Cancer Cooperative Trial Groups (CCTGs). They consider the balanced contribution that a consumer perspective can make to a trial and reflect on the type of contribution they as an individual can make.	***Capability 2.3: Contribute to Cancer Clinical Trial scientific publication content*** Consumers learn about the basic principles, processes and author responsibilities associated with scientific publications. They bring a 'user' perspective to the process and authorship and in doing so learn about the importance of a valid methodology and the rigors of data collection and recording.	***Capability 3.3. Supporting Capable Consumers*** Consumers have knowledge from their own experience and not always as a patient. They are able to represent the views of others and ask key questions. They are motivated, informed and confident of being able to make a difference to the cancer clinical trial research process.
Capability 1.4: How Cancer Clinical Trials are conducted Consumers learn about how clinical trials in cancer are conducted, the policies and regulations that govern cancer clinical trials and how they relate to, but are not limited to research ethics, safety reporting and stopping rules and trial management..	***Capability 2.4: Contribute to the dissemination of information to the broader community*** Effective dissemination of research results requires communication to the broader community. Consumers develop skills in how to review and appraise lay summaries, publications and other documentation intended to communicate trial results and research findings.	

Concepts and Capabilities with eLearning Outcomes

Concept 1: **Understand clinical trial context, concepts and protocols** This concept will provide a foundation of cancer knowledge and an understanding of the cancer clinical trial process. Consumers will be introduced to the fundamentals of cancer research design and will learn about basic statistical concepts and terms. Consumers will not be expected to become statistical experts, but will be provided with experiences that will further their ability to understand and interpret research results.	**eLearning Outcomes** **At the completion of the eLearning activities, consumers should be able to:**
Capability 1.1: Knowledge of Cancer Consumers in CCTGs build on their knowledge of Cancer and specific types and further their understanding of the epidemiology of cancer.	• Describe the basic epidemiology of cancer. • Explain the basic biology of cancer (Identify general characteristics of cancer growth and non- cancer growth). • Match type of cancer (tumour type) to trials group
Capability 1.2: Understanding of Cancer research design Consumers learn about the fundamentals of cancer research design including basic statistical concepts and terms. They explore the concepts of randomization, p values and measures as well as different types of cancer clinical research design.	• Know how cancer research and study aims and objectives are specified, designed and conducted. • Explain data descriptions and sampling. • Discuss basic statistical analysis including hypothesis testing, p-values randomization and different types of cancer clinical trial research design. • Interpret the reporting of results.
Capability 1.3: Understanding of Cancer Clinical Trials Consumers learn about clinical trials and cancer clinical trials research nationally and internationally, funding opportunities within Australia and the role of government and non-government organizations involved in cancer research. They understand about cancer specific clinical trials and the functions of the Cancer Cooperative Trial Groups (CCTGs). They consider the balanced contribution that a consumer perspective can make to a trial and reflect on the type of contribution they as an individual can make.	• Describe the players involved in clinical trials research and their relationships. • Discuss the financial support for clinical trials research • Outline the Australian clinical trials context. • Discuss the consumer contribute to clinical trials
Capability 1.4: How Cancer Clinical Trials are conducted Consumers learn about how clinical trials in cancer are conducted, the policies and regulations that govern cancer clinical trials and how they relate to, but are not limited to research ethics, safety reporting and stopping rules and trial management.	• Outline the framework (ethical and governance) supporting clinical trials research. • Know how clinical trials are developed, conducted, reported and implemented. • Explain the concept of clinical equipoise. • Demonstrate awareness of ethical guidelines (Declaration of Helsinki, Belmont Report, NHMRC National Statement on Research in Humans) • Demonstrate awareness of Good Clinical Practice Guidelines • Demonstrate awareness of subject protection (safety reporting requirements, stopping rules & Safety Data Monitoring Committees) in clinical trials.

Concept 2: **Communicating trial information** Skills in communicating information about clinical trials are essential to consumers providing advice in the context of Cancer Clinical Trial Research. This concept will assist consumers to use and apply these skills and knowledge in the critical appraisal of participant information and capably fulfill the role of the consumer in a Cancer Clinical Trial Group (CCTG).	**eLearning Outcomes** **At the completion of the eLearning activities, consumers should be able to:**
Capability 2.1: Understand the context of 'informed consent' Consumers learn about the legal nature and the elements of informed consent. They examine and explore the risks and costs associated with decision making, and appraise scenarios that may not fulfill the requirements of valid, competent and voluntary consent.	• Describe what constitutes informed consent • Describe personal decision-making in relation to informed consent for clinical trials • Identify flaws in informed consent process • Explain how people are informed about clinical trials research (clinician-patient discussion, research nurse-patient discussion, decision aids & consent documents)
Capability 2.2: Critically appraise Cancer Clinical Trial participant information Consumers examine and review participant information and consent forms, discuss and analyze the suitability of language, format and presentation as materials that are 'easy to read' are more acceptable to a potential research participant. Consumers use checklists that assist them identify ambiguous phrases, technical jargon and socially or culturally inappropriate language. Consumers develop appraisal skills that will assist them to decide if the aims of a study, the treatment schedule, side effects and, risks as set out in the protocol are consistent with the participant information.	• Outline concepts of reading age and readability of documents • Explain the purpose of informed consent documents • Critique the suitability of trial participant consent documents • Outline the process of language translation • Demonstrate how informed consent documents reflect what a trial involves • Describe the constraints related to informed consent.
Capability 2.3: Contribute to Cancer Clinical Trial scientific publication content Consumers learn about the basic principles, processes and author responsibilities associated with scientific publications. They bring a 'user' perspective to the process and authorship and in doing so learn about the importance of a valid methodology and the rigors of data collection and recording.	• Describe the process of scientific publishing • Demonstrate awareness of standards for reporting clinical trials (i.e. CONSORT Statement) • Describe the roles and responsibilities of authors • Demonstrate awareness of requirement for prospective clinical trial registration
Capability 2.4: Contribute to the dissemination of information to the broader community Effective dissemination of research results requires communication to the broader community. Consumers develop skills in how to review and appraise lay summaries, publications and other documentation intended to communicate trial results and research findings.	• Describe how results are communicated • Demonstrate ability to critically appraise trial reports • Convert research findings into lay language

Concept 3: **Develop skills for participating in the cancer clinical trial research process** This concept will assist consumers effectively participate in the Cancer Cooperative Trial Group (CCTG) decision making processes and contribute to committees	**eLearning Outcomes** **At the completion of the eLearning activities, consumers should be able to:**
Capability 3.1: Effective committee membership Consumers appreciate and understand how research committees function, the importance of the committee process and the expectations of an effective committee member. They learn about the need to be organized, prepared and manage time effectively, prioritize and complete actions in agreed timeframes, comment on documentation and other responsibilities that are consistent with the committee terms of reference.	• Describe optimal meeting processes • Describe roles & responsibilities of committee members • Explain the different types of organisational structures underpinning clinical trial groups
Capability 3.2: Effective interpersonal communication skills in meetings and committees Consumers understand the need to develop effective written and verbal communication skills and the value of demonstrating appropriate interpersonal behaviour and professional conduct. Committee members with effective interpersonal skills are familiar with terminology of the CCTG specialty through using glossaries, and seeking clarification as required.	• Demonstrate appropriate communication skills consistent with being an effective committee member • Identify the varied roles that the consumer can have on a committee and the need to adapt accordingly.
Capability 3.3. Supporting Capable Consumers Consumers have knowledge from their own experience and not always as a patient. They are able to represent the views of others and ask key questions. They are motivated, informed and confident of being able to make a difference to the cancer clinical trial research process.	• Demonstrate a capacity to represent and advocate for the views of others